

Speech-Language Pathology and Audiology Board

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STATE OF CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS SPEECH-LANGUAGE PATHOLOGY AND AUDIOLOGY BOARD

Marina Del Rey Hotel 13534 Bali Way Marina Del Rey, CA 90292 (310) 301-1000 July 15, 2004

SPEECH-LANGUAGE PATHOLOGY PRACTICE COMMITTEE MEETING MINUTES

Committee Members Present

James Till, Ph.D., Chairperson Bruce Gerratt, Ph.D. Sherry Washington, M.A.

Committee Members Absent

Vivian Shannon, M.A. Paul Donald, M.D.

Board Members Present

Rebecca Bingea, M.A. Marcia Raggio, Ph.D. Alison Grimes, AuD

Staff Present

Annemarie Del Mugnaio, Executive Officer Lori Pinson, Staff Analyst George Ritter, Legal Counsel Albert Balingit, Legal Counsel

Guests Present

Lesley Mateer, CIAO
Marcia Mathason, SLP
Dennis Van Vleit, AU
Jan Speirs, SLP, Scripps Hospital
Angela Mandas, President California
Speech-Language- Hearing Association
Ed Dunlay, The Chattanooga Group
Dan Duffy, Chattanooga Group
Mike Stringer, Columbia Scientific

I. Call to Order

Chairperson Till called the meeting to order at 4:37 p.m.

II. Introductions

Those present introduced themselves.

III. Discussion of Issue Paper Regarding Speech-Language Pathologists Utilizing Electrical Stimulation for Treatment of Swallowing Disorders

Chairperson Till introduced the discussion and referenced the draft issue paper contained in the meeting packets.

Ms. Del Mugnaio explained the background of the issue and stated that a Board member and a member of the Physical Therapy Association had expressed concern regarding the safety of speech-language pathologists utilizing electrical stimulation for swallowing, given the limited training available to speech-language pathologists. Ms. Del Mugnaio explained that, at the April 15, 2004 Speech-Language Pathology Practice Committee Meeting, the Board reviewed a legal opinion written by legal counsel, Mr. George Ritter, which concluded that electrical stimulation for swallowing is within the scope of practice of a speech-language pathologist. The Board's challenge was to determine whether further regulation of the use of electrical stimulation by speech-language pathologists was necessary to protect the public. After a lengthy discussion, the Board determined that regulations were not necessary at this time, but that an issue paper providing legal guidance should be developed to notify licensees of the legal parameters relative to the use of electrical stimulation for swallowing disorders. Ms. Del Mugnaio noted that the Committee requested that the draft issue paper be available for public comment at the July Speech-Language Pathology Practice Committee meeting. She indicated that she developed the draft paper with the assistance of Mr. Gerratt and thanked him for his contribution. She stated that, once in final form, the issue paper will be available on the Board's website and distributed upon request.

Chairperson Till identified the written comment by Yorik Wijting included in the meeting packets.

Chairperson Till asked the Committee members if they had any comments or concerns with the draft issue paper.

Ms. Washington stated that she believed the issue paper reflected the key points of a licensee's independent responsibility to refrain from participating in any area of practice in which the licensee is not adequately trained or competent. Ms. Washington asked Mr. Dunlay about the Federal Drug Administration (FDA) approval of electrical stimulation devices used to treat swallowing, and whether that approval addressed efficacy of the treatment.

Mr. Dunlay stated that the language referenced in the draft issue paper regarding FDA "approval" should be changed to reflect FDA "clearance." He further stated that the primary focus of the FDA was to ensure that the device and its intended use did not pose a risk to the consumer. However, he indicated that the FDA studies do include data on efficacy. He cited results from the FDA study in which the FDA monitored 892 cases

where the Vital Stim device was used to treat swallowing disorders and found the device safe in every case. He also stated that the report showed 300 cases in which the subjects benefited from the therapy. He referenced other on-going research regarding this device, including that being conducted in Europe by Dr. Eckburg, as well as a study at Children's Hospital in Orange County.

Ms. Speirs commented on the draft issue paper with respect to the reference of "transcutaneous" electrical stimulation, and stated that some may misunderstand the reference to mean a type of pain treatment. She also disputed the statement in the draft issue paper regarding the purported high costs for consumers receiving this treatment, and stated that the electrical stimulation therapy for dysphasia was reimbursable by HMOs with the exception of a mere \$15. Ms. Speirs commented on the Board's skeptical statements in the draft paper regarding the deficiency of peer-reviewed research to support the efficacy of the therapy and the Board's uncertainty of its benefit. She contended that the Board's posture might negatively affect insurance reimbursements, or even a physician's decision to refer a patient for electrical stimulation.

Ms. Del Mugnaio commented that the statements in the draft position paper are based on fact and that their intent is to caution licensees about their use of the method. She stated that the statements are not intended to persuade the reader to support or disregard the merits of the therapy.

The Committee discussed the public comments and agreed to incorporate the changes as follows: change the reference of "FDA approval" to "FDA clearance," strike the word "transcutaneous" and use "electrical stimulation applied to the skin of a patient," and strike the entire sentence regarding the concern of high costs for consumers receiving the treatment. For the purpose of clarity, a grammatical change to the sentence following was suggested to strike the work "Thus."

M/S/C Washington/Gerratt

The Committee voted to recommend to the Board to adopt the draft issue paper as amended and post the document on the Board's website.

There being no further discussion, Chairperson Till adjourned the meeting at 5:20 p.m.

Annemarie Del Mugnaio, Executive Officer